K120818 #1/2

APR 19 2012

510(k) SUMMARY

As required by section 807.92

Submitter	SCIENCE FOR BIOMATERIALS Sciences et Bio Matériaux ZI du Monge F 65100 LOURDES – FRANCE Registration Number : 3004549189
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Trade Name	OTIS-C Plus
510k	SPECIAL 510K
CFR section	21CFR 888.3030
Classification Name	Single/multiple component metallic bone fixation appliances and accessories
Class	II
Product Codes	HRS: PLATE, FIXATION, BONE HWC : SCREW, FIXATION, BONE
Device panel	ORTHOPEDIC
Legally marketed predicate devices	OTIS-C PLUS (K100604 manufactured by SCIENCE FOR BIOMATERIALS

Description: The OTIS-C Plus plate is designed for the stabilization of High Tibial Osteotomy with a medial approach. Anatomically shaped, thin and short, the OTIS-C Plus plate enables mini-invasive surgery. Its locking system provides immediate compression of the graft as well as stable fixation, thus allowing early weight-bearing. The design of the self-tapping OTIS-C Plus screws (unmodified) allows easy and reliable one step locking, without counter-nut, in a simple and concise approach. With its range of twelve screws lengths, fixation can be either mono or bi-cortical, upon the choice of the surgeon.

Intended Use OTIS-C Plus is intended to be used in conjunction with bone screws to provide fixation following Proximal Tibial Opening wedge osteotomies

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Performance data Non clinical performance testing including fretting corrosion, and determination of torsional yield strength, ultimate, insertion and removal torque and pull-out strength demonstrated that OTIS-C Plus system is as safe, as effective, and performs at least as safely and effectively as its predicate devices. Finite Element Method demonstrates that modification to OTIS-C Plus plate do not alter its mechanical behavior or fretting corrosion. No clinical data has been presented.

Substantial equivalence The modified OTIS-C plus plate is substantially equivalent to its predicate device OTIS-C plus plate (K100604). Verification activity and validation activity demonstrate that modified OTIS-C plus plate is as safe, as effective, and performs at least as safely and effectively as its predicate devices.

Preparation date, revised April 19th 2012

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Science for Biomaterials
Science et Bio Materiaux (SMB)
% Mr. Denis Clement
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France F 65100

APR 19 2012

Re: K120818
Trade/Device Name: OTIS-C Plus
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: HRS, HWC
Dated: March 16, 2012
Received: March 22, 2012

Dear Mr. Clement:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K120818

Device Name: OTIS-C Plus

Indications for Use:

OTIS-C Plus is intended to be used in conjunction with bone screws to provide fixation following Proximal Tibial Opening wedge osteotomies

Prescription Use ✓ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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